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STATE OF DELAWARE
BOARD OF PHARMACY

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PUBLIC MEETING NOTICE:	BOARD OF PHARMACY
DATE AND TIME:	Wednesday, August 17, 2016 9:30 am
PLACE:	Conference Room A, 2 nd Floor Cannon Building 861 Silver Lake Blvd., Dover, DE 19904
APPROVED:	September 21, 2016

MEMBERS PRESENT

David W. Dryden, R.Ph., J.D., Executive Secretary
Susan Esposito, R.Ph., Professional Member, President
Hooshang Shanehsaz, R.Ph., Professional Member, Vice President
Bonnie Wallner, R.Ph., Professional Member
Kimberly Robbins, R.Ph., Professional Member
Tejal Patel, PharmD, Professional Member
Jay Galloway, Public Member
Julia Wheatley, Public Member

MEMBERS ABSENT

DIVISION STAFF/DEPUTY ATTORNEY GENERAL PRESENT

Eileen Kelly, Deputy Attorney General
Christine Mast, Administrative Specialist III
Michelle McCreary, Pharmacist Compliance Officer

ALSO PRESENT

Lauren M. Navarre
Elizabeth Hauss
Suzanne Raab-Long
Evan Landa
Johanna Rodriguez
Chinedum Amakwe
Joel L Copper
Michelle Crosier
Bill Irvin
Jaime Frink
Cheryl Heiks
Rachael Pontikes
Brian Redding
Anna Campagna
Anthony Gabriel
Dr. Bob Thompson
C. Scott Kidner
Randy Farmer

CALL TO ORDER

Ms. Esposito called the meeting to order at 9:35 a.m.

REVIEW OF MINUTES

A motion was made by Mr. Shanehsaz and seconded by Ms. Wheatley to approve the meeting minutes for June 15, 2016. Ms. Patel abstained and the motion carried.

UNFINISHED BUSINESS

A motion was made by Mr. Shanehsaz seconded by Ms. Patel to move forward in the agenda to New Business IV.O FDA Compounding Regulation – Veterinary Compounding. The motion carried.

IV.O FDA Compounding Regulation Revision – Veterinary Compounding

Ms. Kelly provided the members of the Board copies of the Delaware Compounding statute and regulations references, Food and Drug Administration references to Public Law, FDA 503A Guidance document, FDA 503B Guidance document, Email correspondence and Draft Guidance received from Brian T. Kehoe, Dir. Intergovernmental Affairs, FDA, letter from Eileen Kelly, Deputy Attorney General for the Board of Pharmacy, outlining “Compounding for Veterinary Use” concerns voiced by the Delaware Veterinary Medical Association. Ms. Kelly reviewed these documents with the Board. The Board discussed in length the confusion created by the FDA Draft Guidance and the enforcement of such. Ms. Rachel Pontikes, Duane, Morris, LLP presented the Board with draft language relating to Veterinary Compounding and the FDA Guidance language. Ms. Pontikes states that 503A and 503B are for Human Drugs and are not intended to apply to Veterinary Compounding and/or animal health. The Board continued discussion regarding clarifying the statutory language to allow office use of compounded medications for veterinary medicine. Ms. Michelle Crosheir, VMD relayed her concerns regarding the inability to treat animal patients with necessary compounded medications, particularly during nighttime and weekend hours. Mr. Dryden relayed information received from Brian T. Kehoe, Dir. Intergovernmental Affairs, FDA regarding the position of the FDA and veterinary compounding. A motion was made by Mr. Shanehsaz seconded by Ms. Robbins to move this agenda item to the Legislative Committee to review and formulate proposed statute changes to assist with this issue. The motion carried.

Statutory and Regulatory Discussion

Review of Substantially Similar Crimes Listing – tabled for further review.

Telemedicine Pharmacy Statute and Regulations Changes – Ms. Kelly has prepared draft regulations for the Board to review. The Board will need to develop rules and regulations to support the statute for telemedicine. Ms. Kelly asked the Board to review the draft guidance she provided from other states and return to discuss draft regulations changes. A motion was made by Mr. Shanehsaz seconded by Ms. Robbins to move this agenda item to the Legislative Committee. The motion carried.

A motion was made by Ms. Patel seconded by Ms. Robbins to move forward in the agenda to New Business IV.K.4 Cadbury Senior Living Lewes, De. – MedSelect Automated Dispensing.

Mr. Evan Landa, Innovative Pharmacy presented to the Board specific information related to the automated system for review. A motion was made by Ms. Robbins seconded by Ms. Wallner to approve the MedSelect-Flex Device. The motion carried.

A motion was made by Mr. Shanehsaz seconded by Ms. Patel to move forward in the agenda to New Business IV.B Delaware Health Information Network (DHIN) – Mr. Randall J Farmer, Chief Operating Officer provided the Board with a handout which outlines an overview of DHIN. The handout provided information on Participation, Senders and Receivers of Information, New Services Provided and the benefit to public safety. Ms. Robbins wanted to know when the DHIN information would be available to pharmacists to assist with public safety, and diversion. Mr. Farmer responded that all health care professionals would benefit from access however, statutory requirements currently prohibit access. Theses statute and regulations are being reviewed for possible revision to include pharmacists.

3PL Licensure Discussion – Ms. Kelly is continuing in the preparation of draft regulations.

Ongoing - Provision for Disciplinary Action – Ms. Kelly is preparing a draft bill for presentation to the director for review.

Ongoing - Clarification of 24 **Del. C.** §2512(e) (f), Inactive Status - Ms. Kelly is preparing a bill for presentation to the director for review.

Ongoing - Patient Practitioner Relationship & E-Prescribing Update – the bill is currently being reviewed by prospective legislative sponsorship.

Re-Review of Consent Agreement – Peter W. Hauss

A motion was made by Ms. Wallner seconded by Mr. Shanehsaz to approved the consent agreement as written. The motion carried.

PRESIDENT’S REPORT

Ms. Esposito stated that she will replace Ms. Patel on the AWSAM Committee. Ms. Sandy Robinson will attend the next meeting with Ms. Esposito during the transition as the Board of Pharmacy Representative.

Ms. Esposito and Mr. Dryden conducted a counseling session with a Pharmacist related to a medication error at the request of the Deputy Attorney General which was the result of a hearing.

NEW BUSINESS

Ms. Esposito read into the record the following ratifications:

Pharmacist and Intern Licensure Approval Ratifications

Pharmacist:

Michael	D	Reedy	A1-0004950
Jillian	Patricia	Dougherty	A1-0004951
Dylan	Robert	Howery	A1-0004952
Dennis	Dy	Nuguid	A1-0004953
Mahlet		Aklile	A1-0004954
John	D	Ganther	A1-0004955
Aisha	A	Rauf	A1-0004956
Vy	Lam	Nguyen	A1-0004957
Jeffrey		Liu	A1-0004958
Jack	W.	Williams	A1-0004959
Mary	L	Lurwick	A1-0004960
Sejal		Marvania	A1-0004961
Nicole	J.	Lombardo	A1-0004962
Susan	Reichenbaugh	Sherbin	A1-0004963
Raymond	Michael	Snyder	A1-0004964
Kyle	M	Vaitukaitis	A1-0004965
Michael	A.	Dryslowski	A1-0004966
Kelsey	Colleen	McIntyre	A1-0004967
Emily	Beth	Mills	A1-0004968
Melissa	Elizabeth	Buff	A1-0004969
David	M.	Sharkey	A1-0004970
Roman	R	Steiner	A1-0004971
Blair	G.	Heckel	A1-0004972
Alison	Mikell	Forrest	A1-0004973
Bess	P	Lynch	A1-0004974
Mathew	J	Mason	A1-0004975

Ebony	R.	Cook	A1-0004976
Vivek	K	Kataria	A1-0004977
Adrienne	Isabella	Herman	A1-0004978
Izetta	Chaunte'	Henry	A1-0004979
Lauren	M	Jansing	A1-0004980
William	Michael	Clifton	A1-0004981

Pharmacist Intern:

Robert	Rudolf	Svenson	A7-0002429
Punam		Patel	A7-0002430
Lauren	A	Englert	A7-0002431
Quynh-Nhu		Truong	A7-0002432
Alyssa	Xuan	Nguyen	A7-0002433
Victoria	T	Drews	A7-0002434
Edwin	Douglas	Allen, Jr.	A7-0002435

A motion was made by Ms. Patel and seconded by Mr. Shanehsaz to approve the ratification of the Pharmacist/Intern applications. The motion unanimously carried.

Non-Resident Pharmacy Licensure Approval Ratifications

A9-0001857	Wedgewood Village Pharmacy LLC.
A9-0001858	Long's Drugs of Lexington, South Carolina, Inc.
A9-0001859	Biologics, Inc.
A9-0001860	US Compounding
A9-0001861	Pharmacare Plus
A9-0001862	Horizon Pharmacy
A9-0001863	DQD Enterprise Corporation
A9-0001864	Causey's Pharmacy, Inc
A9-0001865	Optime Care, Inc
A9-0001866	Riverside Pharmacy Associates LLC
A9-0001867	Allcare Pharmacy, Inc.
A9-0001868	Total Home Health Care, Inc.
A9-0001869	Millennium Pharmacy Systems, LLC
A9-0001870	Synergy Pharmacy, LLC
A9-0001871	Bergen Pharmacy
A9-0001872	Assurance Consolidated Pharmacy
A9-0001873	ReCept Pharmacy # 1
A9-0001874	FT FRX LLC
A9-0001875	At Home IV Infusion Professional, Inc
A9-0001876	Heritage Biologics, Inc.
A9-0001877	Maxxon Home Health Care, LLC

A motion was made by Ms. Robbins and seconded by Mr. Shanehsaz to approve the ratification of the Non Resident Pharmacy applications. The motion unanimously carried.

Wholesale Distributor Licensure Approval Ratifications

A4-0002313	Eli Lilly and Company
A4-0002314	KeySource Acquisition, LLC
A4-0002315	Focus Health Group
A4-0002316	Jacobus Pharmaceutical Company, Inc
A4-0002317	Fagron Sterile Services

A4-0002318	Reliable Pharmaceutical Returns LLC
A4-0002319	Protein Sciences Corporation
A4-0002320	Protein Sciences Corporation
A4-0002321	Noramco, Inc.
A4-0002322	VistaPharm, Inc.
A4-0002323	Dynasty Pharmaceuticals, Inc.
A4-0002324	Optime Care, Inc
A4-0002325	The Proctor & Gamble Distributing, LLC
A4-0002326	Supplies Distributors, Inc.
A4-0002327	GenPak Solutions LLC d/b/a Eth iPak
A4-0002328	Actavis Pharma, Inc.

A motion was made by Ms. Robbins and seconded by Ms. Patel to approve the ratification of the Wholesale Distributor applications. The motion unanimously carried.

Medical Gas Dispensers

A2-0000141	Dusara Corporation
A2-0000142	Dusara Corporation

A motion was made by Ms. Robbins and seconded by Ms. Patel to approve the ratification of the Medical Gas Distributor applications. The motion unanimously carried.

Retail Pharmacy Licensure Approval Ratification

A3-0000581	ShopRite Pharmacy #558
A3-0001004	Express Pharmacy

A motion was made by Ms. Robbins and seconded by Ms. Patel to approve the ratification of the Retail Pharmacy applications. The motion unanimously carried.

Pharmacy Manufacturer Approval Ratification

None

Outsourcing Facility

AA-0000026	PharMEDium Services, LLC
AA-0000027	Fagron Sterile Services
AA-0000028	KRS Global Biotechnology, Inc.

A motion was made by Ms. Robbins and seconded by Ms. Patel to approve the ratification of the Outsourcing Facility applications. The motion unanimously carried.

Pharmacist-In-Charge Interviews

Ms. Robbins conducted PIC interviews with the following Pharmacists in Charge:

PIC, Johnanna Rodriguez, Walgreens #11022 Bear, DE.

PIC, Chinedum Awakwe, Synergy Express Pharmacy, New Castle, DE.

PIC, Lauren Navarre, Walgreens, Wilmington, DE.

Consultant PIC, Elizabeth Hauss, Delaware Home for the Chronically Ill, Smyrna, DE.

Board Review of Facility Applications

Acro Pharmaceutical Service, LLC. (Sharon Hill, PA), a motion to approve the application was made by Mr. Shanehsaz and seconded by Mr. Galloway. The motion unanimously carried.

Humana Pharmacy (Phoenix, AZ), a motion to approve the application was made by Mr. Shanehsaz and seconded by Ms. Wallner. Ms. Robbins was not present. The motion carried.

Humana Pharmacy (West Chester, OH), a motion to approve the application was made by Mr. Shanehsaz and Seconded by Mr. Galloway. The motion unanimously carried.

Continuing Education Review

Brooke Darmstadter, a motion was made by Ms. Robbins seconded by Mr. Galloway to approve continuing education credits for 10.875 “Johns Hopkins University School of Medicine”.

Medical Society of Delaware, a motion was made by Ms. Robbins seconded by Mr. Shanehsaz to approve the continuing education provider application through September 30, 2018. The motion carried.

Pharmacist & Pharmacy - Discussion/Action Items

Alert – Midwife Medication Administration – Mr. Dryden stated that an alert was sent to inform that Midwives have been granted authority to administer limited drugs to patients.

Medicine Vending Machine – MEDS BOX (PharmRX24) – Gayane Badalian-Very, MD

Mr. Dryden provided the Board with the information sent by Dr. Badalian-Very for review. The Board stated that they could not support this type of vending machine due to violation of current statute or regulation.

Excel Pharmacy, Rose Niklewicz – Central Fill Across State Lines

The Board reviewed the information provided the information and stated that current statute or regulation would not permit this request.

Curtis Bare CE Audit Discipline Re-Review

Mr. Dryden provided the Board with Mr. Bare’s request to reverse the disciplinary action for non-compliance of continuing education for the 2012-2014 renewal period due to him being deployed. The Board reviewed the submitted materials. Ms. Kelly stated that there must be grounds to vacate this order. She asked what would those grounds be? The Board asked that Mr. Bare provide additional information regarding specifics as to why he is requesting the reversal of the disciplinary action against his license. Mr. Dryden will draft a letter to Mr. Bare.

Immunizing Pharmacist Certificate/Education Program Review

Ms. Mast provided the Board with Immunizing Educational Certificate as well as CPR Credentials from Canada. The Canadian program is not an approved program in Delaware. Programs outside the United States are not accepted by the Delaware Board.

COMMITTEE REPORTS

Legislative – Jay Galloway, Kim Robbins, Tejal Patel, Hooshang Shanehsaz and David Dryden

No Report

Continuing Education – Bonnie Wallner, Tejal Patel and David Dryden:

No Report

Consumer Affairs – Ken Sellers, Jay Galloway and Julia Wheatley

No Report

Professional Liaisons – Kim Robbins, Tejal Patel and Hooshang Shanehsaz:

No Report

Controlled Substance Liaisons – Tejal Patel, Hooshang Shanehsaz, Jay Galloway and David Dryden:

No Report

EXECUTIVE SECRETARY, INSPECTION REPORT - David Dryden, Michelle McCreary

Mr. Dryden reported that the NABP .pharmacy domain is up and running. Mr. Dryden, Ms. McCreary, Ms. Wallner and Mr. James Kaminski have been conducting the annual MPJE questions review for NABP. Mr. Dryden had to collect pharmaceutical drugs from a pharmacy destroyed by fire in Milton, De. He stated that the pharmacy was completely destroyed with the exception of the safe. The drugs in the safe were retrieved and transported to a safe location to be destroyed through a reverse distributor. There were two robberies---one at the Georgetown Pharmacy in Georgetown, DE and the other at a Rite Aid pharmacy in Wilmington, DE. He took a report, reviewed video footage and drafted letters accordingly. Mr. Dryden will add information on what to do during a robbery in the next edition of the newsletter.

Michelle McCreary reported that she completed the following Inspections:

July

2 – Opening Inspections

1 – Follow-up Inspection

1 – Routine Inspection

August

4– Nursing Home Inspections

Election of Officers

Board of Pharmacy statute states terms are for 3 years. No election is required at this time.

BOARD CORRESPONDENCE

NABP-NAPLEX Waiting Period Policy Changes – NABP is changing their waiting period on November 1, 2016 from 91 days to 45 days. This will require the Board of Pharmacy to make a regulations revision to reflect such. Ms. Kelly will provide the board with the proposed changes during a future meeting.

Containment Technologies Group – NABP Endorsement of CriticalPoint, LLC. – The board was provided the letter for review and had no opinion.

NEWSLETTER UPDATES

None

OTHER BUSINESS BEFORE THE BOARD

None

PUBLIC COMMENT

None

NEXT SCHEDULED MEETING

The next meeting is scheduled for September 21, 2016 at 9:30 Am., 1st Floor Conference Room.

ADJOURNMENT

There being no other business before the Board a motion to adjourn the meeting was made by Mr. Shanehsaz and seconded by Ms. Patel at 12:00 pm. The motion unanimously carried.

Respectfully submitted,



Christine Mast
Administrative Specialist III
Liaison, Board of Pharmacy